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TO : Commissioner for Patents
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FROM : Oleg F. Kaplun, Esq. of Fay, Kaplun & Marcin, LLP

DATE : March 10, 2008

SUBJECT : U.S. Patent Appln. Serial No. 10/807,590
for *Dual Lumen Port with F-Shaped Connector*
Inventor(s): Girard et al.
Our Ref.: 10123/04201

NUMBER OF PAGES INCLUDING COVER : 21

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Attorney Docket No. 10123/04201 (03-369US)

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Inventor(s) : Girard et al.
 Serial No. : 10/807,590
 Filed : March 24, 2004
 For : Dual Lumen Port With F-Shaped Connector
 Group Art Unit : 3763
 Confirmation No. : 3798
 Examiner : Matthew F. DeSanto

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By: Date: March 10, 2008
 Oleg F. Kaplun (Reg. No. 45,559)

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 A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: March 10, 2008

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Attorney Docket No. 10123/04201 (03-369US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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PATENT

Attorney Docket No.: 10123 - 04201

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

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| In re Application of: |) | |
| |) | |
| Girard et al. |) | |
| |) | |
| Serial No.: 10/807,590 |) | Group Art Unit: 3763 |
| |) | |
| Filed: March 24, 2004 |) | Examiner: M. DeSanto |
| |) | |
| For: DUAL LUMEN PORT WITH F-SHAPED CONNECTOR |) | Board of Patent Appeals and Interferences |
| |) | |

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed February 7, 2008, and pursuant to 37 C.F.R. § 41.37, Appellants present this appeal brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1 - 10, 13-16, and 18-28 in the Final Office Action dated November 1, 2007. The appealed claims are set forth in the attached Claims Appendix.

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Serial No.: 10/807,590

Group Art Unit: 3763

Attorney Docket No.: 10123 - 04201

1. Real Party in Interest

This application is assigned to NAMIC/VA, Inc., the real party in interest.

2. Related Appeals and Interferences

There are no other appeals or interferences which would directly affect, be directly affected by, or have a bearing on the instant appeal.

3. Status of the Claims

Claims 11, 12, and 17 have been cancelled. Claims 1 - 10, 13-16, and 18-28 stand rejected in the Final Office Action. The final rejection of claims 1 - 10, 13-16, and 18-28 is being appealed.

4. Status of Amendments

All amendments submitted by the Appellants have been entered.

5. Summary of Claimed Subject Matter

This summary associates the claimed invention with certain subject matter of the specification. Nevertheless, since this association is only exemplary, the scope of the claimed invention is not limited to the description contained herein. Moreover, as an exemplary summary, this description does not purport to exhaustively list every place in the specification that supports the claimed features.

In one aspect of the present invention, as exemplified in claim 1, a port for subcutaneous implantation, comprises a housing 102 provided with first and second wells 104, 106 formed therein (Specification at [0018]; Figure 1). The port further includes a substantially F-shaped flow element 120 including first and second lumens 112, 114 extending therethrough.

(Specification at [0019]; Figure 1). In an operative configuration the F-shaped flow element 120 is coupled to the housing 102 with a proximal end of each of the lumens 112, 114 in fluid

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communication with a respective one of the first and second wells 104, 106 for receiving fluid therefrom. (Specification at [0019]; Figure 1). Distal ends of each of the lumens 112, 114 form outlets 116, 118, each outlet being coupleable to a lumen of a medical catheter. (Specification at [0022]; Figure 1). The F-shaped flow element includes first and second arms 128, 130 extending from a trunk 132 with the first lumen 112 extending through the first arm 128 to the trunk 132 and the second lumen 114 extending through the second arm 130 to the trunk 132, the first and second lumens being separated from one another within the trunk. (Specification at [0020]; Figure 1). The first arm 128 includes a first portion extending from an intersection with the second arm 130 substantially parallel to the trunk 132 and a second portion extending substantially parallel to the second arm 130, wherein the first portion of the first arm 128 is separated from the housing by a gap (Specification at [0020]; Figure 1).

In another aspect of the present invention, as exemplified by claim 13, a dual well port device comprises a housing 102 defining first and second wells 104, 106 disposed along an axis of the housing 102. (Specification at [0018]; Figure 1). The port also includes an F-shaped flow element 120 including separate lumens 112, 114 independent of one another. (Specification at [0019]; Figure 1). The first lumen 112, when the flow element 120 is in an operative configuration coupled to the housing 102, is fluidly connected to the first well 104 and has an arm portion 128 extending at a first angle relative to the axis. (Specification at [0020]; Figure 1). When in the operative configuration, the second lumen 114 is fluidly connected to the second well 106 and includes an arm portion 130 extending at a second angle relative to the axis. (Specification at [0020]; Figure 1). The F-shaped flow element includes a trunk 132 enclosing trunk portions of the first and second lumens 112, 114, the first arm 128 including a first portion extending from an intersection with the second arm 130 substantially parallel to the trunk 132 and a second portion extending substantially parallel to the second arm 130, wherein the first portion of the first arm 128 is separated from the housing 102 by a gap. (Specification at [0020]; Figure 1).

In another aspect of the present invention, as exemplified by claim 19, a method of

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infusing fluids into a patient comprises implanting distal ends of first and second catheter lumens into a blood vessel. (Specification at [0013]). The method involves fluidly connecting each of the first and second catheter lumens to first and second flow element lumens 116, 118 of an F-shaped flow element 120, the first flow element lumen 116 extending through a trunk 132 of the F-shaped flow element and through the first arm 128 to fluidly connect to a first well 104 of a dual well port and the second flow element lumen 118 extending through the trunk 132 and a second arm 130 to fluidly connect to a second well 106 of the port, wherein the first and second flow element lumens 116, 118 are separated from one another in the trunk 132, the first arm 128 including a first portion extending from an intersection with the second arm 130 substantially parallel to the trunk 132 and a second portion extending substantially parallel to the second arm 130, wherein the first portion of the first arm 128 is separated from the housing 102 by a gap. (Specification at [0006] and [0018]-[0022]). The method further involves introducing a first fluid into the first well 104, and introducing a second fluid into the second well 106 so that the first and second fluids are passed into the blood vessel without intermingling with one another prior to leaving the distal ends of the first and second catheter lumens. (Specification at [0006]).

6. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 1 - 10, 13 - 16, and 18 - 28 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,892,518 to Cupp et al. (hereinafter "Cupp") in view of United States Patent No. 5,542,923 to Ensminger et al. ("Ensminger").
- II. Whether claims 1 - 10, 13 - 16, and 18 - 28 are unpatentable under 35 U.S.C. § 103(a) as obvious over Ensminger et al.

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7. Argument

I. Rejection Based On Cupp And Ensminger

Claims 1-10, 13-16, and 18-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cupp in view of Ensminger et al. The disagreement with the Examiner is on whether the prior art teaches an F-shaped flow element. The prior art, as understood by Appellants, does not teach a flow element that can reasonably be regarded as having the shape of the letter F. The Examiner disagrees, stating in the Advisory Action that Appellants "fail[] to understand the full scope of the claim" and that they are "reading limitations into the claim since the claim fails to fully describe the letter F shape via the claim language." If an object is described as having the shape of an F, that statement ought to be understood as necessarily implying certain traits that distinguish the object from other objects. Just as the word "ball" implies roundness, it also implies certain exclusions such as "not square" or "not angular." There is no need to be explicit with what is so obviously implicit. The realization that words of physical description necessarily imply or exclude certain traits not only is non-controversial, it ought to be regarded as the approach by which one of ordinary skill in the art arrives at an understanding of the claimed invention.

The Advisory Action commentary of the Examiner appears to negate this common sense approach to the interpretation of language. The Examiner charges Appellants with the failure to "fully describe" the F-shape term, but why should Appellants have to resort to such pedantry when there is common agreement among the overwhelming majority of English speakers as to what an "F" looks like? And why should that universal consensus not be imputed to one of ordinary skill? By calling something F-shaped, that means it is not A-shaped, B-shaped, C-shaped, etc. If Cupp calls connector 107 a Y connector and illustrates it with at least a passing resemblance to the letter Y, then the connector should not be regarded as resembling an F. The claim even recites that the F-shaped flow element includes "substantially parallel" arms, but the Examiner discounts the significance of this language because the "claims never recite two

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parallel lumens." Advisory Action at page 2. Appellants are unsure of what to make of this needless hair-splitting. Does the word "substantially" nullify the word "parallel", so that two lines intersecting at a point to form the letter "V" would be covered by the term? Again, by employing common sense to avoid such an absurdity, one of ordinary skill in the art would understand that "substantially parallel" simply means not perfectly parallel. In terms of the claim, "substantially parallel" ought to mean not only that the arms do not intersect at the trunk, but that the projection of their axes would not intersect for a significant distance beyond the trunk. This is merely a common sense implication that need not be expressly stated in the claim. The prior art shows arms that intersect on the trunk. Thus, they should not be regarded as "substantially parallel."

The following substantially repeats what was stated in the Response to the final Office Action.

The Examiner maintains that Cupp shows an F-shaped connector. In the rejection, the Examiner points to the port assembly of Figure 2, in particular, the eccentrically shaped Y-connector 107. As much of a stretch it is to describe this connector as Y-shaped, the contention that this connector looks like an "F" is beyond the pale. If a person had traced the shape of this connector on paper, what person, in fact, what school child, would identify it as an "F"? An "F" written to look like connector 107 would not merely be an example of sloppy penmanship that bears at least a minimal resemblance to an "F," since it would not be intelligible as an "F." In connector 107, the two arms are not parallel to each other; they are not even close to being parallel. The arm at the distal end of the connector barely deviates from the axis of the trunk, a far cry from the ninety degree deviation for the upper arm of the traditional "F." Although the connector 107 barely resembles a "Y", at least it shares with a traditionally shaped "Y" the feature of two arms that extend away from each from a common point on a trunk. Every visual feature that uniquely distinguishes a traditionally formed "F" from every other letter is thus absent from the Y connector 107. The diagram that the Examiner provides at the end of the office action is unhelpful since it engages the issue at a level of generality that fails to address the

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issue at the level of specificity recited in the claim. The claim calls for the first and second arms to be parallel, yet the Examiner does not provide an argument showing how the first and second portions identified as such in the diagram are parallel, nor could he, since these portions are quite clearly extending along respective axes that intersect each other.

As to the contention by the Examiner that the Appellants have not shown any criticality for the particular shape of the connector, where is the authority by which the Examiner can substitute an allegation of non-criticality for hard evidence or scientific reasoning? The Examiner is charged with rejecting only those claims for which evidence has been found that demonstrates objectively the unpatentability thereof. A cavalier assertion of non-criticality falls short of this standard of proof. As for the assertion that the shape is a mere design choice, Appellants traverse this assertion and note that the Examiner has not cited any evidence showing an F-shaped flow element.

As for the dependent claims, Appellants submit that they are patentable for at least the same reasons given above.

Appellants also argue for each dependent claim independently of the independent claims. What is also striking about this office action, as well as the previous one, is that the Examiner does not explicitly consider any of the limitations of the dependent claims, except for addressing the angle of the arms in a general, non-specific way. Not one sentence, not even a clause, in either office action is directed to the other dependent claims. Where is the discussion of the partition of claim 2, the semicircular cross section of claim 8, or the flow control valve of claim 10, to name just three of the dependent claims ignored in the body of the rejections? Including the claims reciting the angles of the arms, which the Examiner never expressly addresses but merely dismisses as a mere design choice, the Examiner simply has failed to make a prima facie case of unpatentability for any dependent claim.

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II Rejection Based On Ensminger

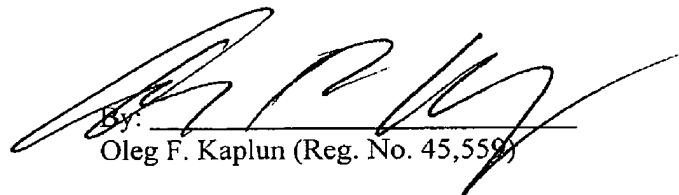
Similarly, with respect to Ensminger, the Examiner has not shown how this reference overcomes any of the deficiencies of Cupp. Even more clearly than the connector 107 of Cupp, the connector 90 in Ensminger shows a pair of arms 92 and 92' that are oriented in the way traditionally conceived for the letter Y and thus not in the way commonly understood for the letter "F." Had the claims never recited an F-shaped connector, Appellants submit that it would not have occurred to the Examiner to assert that what clearly resembles (or in the case of Cupp is at least clearly identified) a Y shape is in fact F-shaped. One of ordinary skill certainly would not view the matter in this way, given that such a person would have judged the issue by determining which letter, traditionally conceived, most closely resembles the shape of the Ensminger connectors. Therefore, in view of this discussion, independent claims 1, 13, 19, and 22 are not rendered unpatentable by Ensminger. As for the dependent claims, they too are patentable for the same reasons given above.

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8. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims.

Respectfully submitted,


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CLAIMS APPENDIX

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1. A port for subcutaneous implantation, comprising:

a housing including first and second wells formed therein; and

a substantially F-shaped flow element including first and second lumens extending therethrough wherein, when in an operative configuration the F-shaped flow element is coupled to the housing with a proximal end of each of the lumens in fluid communication with a respective one of the first and second wells for receiving fluid therefrom, and wherein distal ends of each of the lumens form outlets, each outlet being coupleable to a lumen of a medical catheter, the F-shaped flow element including first and second arms extending from a trunk with the first lumen extending through the first arm to the trunk and the second lumen extending through the second arm to the trunk, the first and second lumens being separated from one another within the trunk, the first arm including a first portion extending from an intersection with the second arm substantially parallel to the trunk and a second portion extending substantially parallel to the second arm, wherein the first portion of the first arm is separated from the housing by a gap.

2. The port according to claim 1, wherein the first and second lumens are separated from one another in the trunk by a partition extending across an interior space thereof.

3. The port according to claim 1, wherein the first and second wells are positioned along an axis of the housing and wherein the first and second arms extend from the trunk at an angle relative to an axis.

4. The port according to claim 3, wherein, when in the operative configuration, the trunk

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extends substantially parallel to the axis.

5. The port according to claim 4, wherein the first and second arms extend from the trunk at an angle of between about 30 degrees and about 60 degrees relative thereto.

6. The port according to claim 1, wherein the first and second arms have a substantially circular cross-sectional shape.

7. The port according to claim 1, wherein the trunk has a substantially circular cross-sectional shape.

8. The port according to claim 1, wherein the first and second arms have a substantially semi-circular cross section.

9. The port according to claim 1, wherein the trunk has a substantially semi-circular cross section.

10. The port according to claim 1, further comprising at least one flow control valve located between a first one of the wells and the corresponding outlet.

13. A dual well port device, comprising:

a housing defining first and second wells disposed along an axis of the housing;
and

an F-shaped flow element including separate lumens independent of one another,
the first lumen, when the flow element is in an operative configuration coupled to the

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housing, being fluidly connected to the first well and having an arm portion extending at a first angle relative to the axis and wherein, when in the operative configuration, the second lumen is fluidly connected to the second well and includes an arm portion extending at a second angle relative to the axis, the F-shaped flow element including a trunk enclosing trunk portions of the first and second lumens, the first arm including a first portion extending from an intersection with the second arm substantially parallel to the trunk and a second portion extending substantially parallel to the second arm, wherein the first portion of the first arm is separated from the housing by a gap.

14. The dual well port device according to claim 13, further comprising a partition of the trunk separating the trunk portions of the first and second lumens.
15. The dual well port device according to claim 13, wherein the first angle is substantially the same as the second angle.
16. The duel well port device according to claim 13, wherein, when the F-shaped flow element is in the operative configuration, the trunk is disposed substantially parallel to the axis.
18. The dual well port device according to claim 13, wherein a flow control valve is disposed between the first well and an outlet of the first lumen.
19. A method of infusing fluids into a patient, comprising:
 - implanting distal ends of first and second catheter lumens into a blood vessel;
 - fluidly connecting each of the first and second catheter lumens to first and second flow element lumens of an F-shaped flow element, the first flow element lumen

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extending through a trunk of the F-shaped flow element and through the first arm to fluidly connect to a first well of a dual well port and the second flow element lumen extending through the trunk and a second arm to fluidly connect to a second well of the port, wherein the first and second flow element lumens are separated from one another in the trunk, the first arm including a first portion extending from an intersection with the second arm substantially parallel to the trunk and a second portion extending substantially parallel to the second arm, wherein the first portion of the first arm is separated from the housing by a gap;

introducing a first fluid into the first well; and

introducing a second fluid into the second well so that the first and second fluids are passed into the blood vessel without intermingling with one another prior to leaving the distal ends of the first and second catheter lumens.

20. The method according to claim 19, further comprising injecting each of the first and second fluids into the corresponding ones of the first and second wells through a corresponding septum.

21. The method according to claim 19, further comprising connecting the F-shaped flow element to the dual well port.

22. An F-shaped connector for a dual well port, comprising:

a trunk including first and second connector lumens extending therethrough, distal ends of each of the first and second connector lumens being connectable to proximal ends of separate catheter lumens;

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a first arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the first connector lumen, a proximal end of the arm portion of the first connector lumen being fluidly connectable to a first of the dual well port; and

a second arm of the trunk extending from the trunk at an angle relative thereto and including an arm portion of the second connector lumen, a proximal end of the arm portion of the second connector lumen being fluidly connectable to a second well of the dual well port, wherein the first and second connector lumens are separate from one another so that fluid from the first well does not mix with fluid from the second well before reaching the distal ends of the first and second connector lumens, the first arm including a first portion extending from an intersection with the second arm substantially parallel to the trunk and a second portion extending substantially parallel to the second arm, wherein the first portion of the first arm is separated from the housing by a gap.

23. The connector according to claim 22, further comprising a partition of the trunk separating trunk portions of the first and second lumen connector lumens from one another.
24. The connector according to claim 22, further comprising an attachment for a flow control valve at an inlet of at least one of the first and second arms.
25. The connector according to claim 22, wherein the first and second arms are connectable to the port at an angle relative to an axis of the port.
26. The connector according to claim 25, wherein the angle relative to the axis is between about 30 degrees and about 60 degrees.

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27. The connector according to claim 22, wherein the trunk is adapted to be disposed when connected to the dual well port at an angle selected to minimize a width of the dual well port.
28. The connector according to claim 22, wherein the trunk has one of a substantially circular and substantially semi-circular cross-sectional shape.

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EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

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RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.